RECORD
AND
BRIEF

Nos. 15-1039 and 15-1195

Supreme Court, U.S.
FILED
DEC 20 2016
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

SANDOZ INC.,

Petitioner,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Respondents.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Cross-Petitioners,

v.

SANDOZ INC.,

Cross-Respondent.

ON PETITION AND CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

SUPPLEMENTAL BRIEF FOR RESPONDENTS AND CROSS-PETITIONERS

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Respondents Amgen Inc. and Amgen Manufacturing Limited state the following:

Amgen Inc. is a publicly held corporation. Amgen Inc. has no parent corporation and no publicly held corporation owns 10% or more of its stock.

Amgen Manufacturing Limited is a wholly owned subsidiary of Amgen Inc. Apart from Amgen Inc., there is no publicly held corporation with a 10% or greater ownership in Amgen Manufacturing Limited.

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SUPPLEMENTAL BRIEF FOR RESPONDENTS AND CROSS-PETITIONERS

The Government would render the patent provisions of subsection 262(*l*) a dead letter. It contends that an Applicant cannot be compelled to comply with either subparagraph 262(*l*)(2)(A) or subparagraph 262(*l*)(8)(A). (*See* U.S. Br. 13, 21.) On the Government's reading, unless an Applicant happens to have securities-law disclosure obligations, it may keep secret the fact it has filed an aBLA, refuse to provide notice, and surprise the Sponsor and the courts when the FDA eventually announces it has licensed the Applicant's biosimilar. While the Government asserts that subsection 262(*l*) was intended to accelerate patent litigation, its reading of the statute would permit Applicants to delay that litigation until commercial marketing begins and promote launch-at-risk tactics that threaten continuity of patient care.

That is an untenable reading of the BPCIA. It would wreak havoc on the market, on Sponsors, and on the federal courts. Nothing in the text of the statute, its surrounding context, or the purpose of the statute supports that reading. It defies logic that Congress would wrestle for years over biosimilar legislation and enact an intricate, integrated statute that is rendered optional simply by limiting the scope of declaratory-judgment actions.

The flaws in the Government's interpretation reinforce all the other reasons that the Court should deny Sandoz's petition and leave undisturbed the Federal Circuit's unanimous holding that the 180-

day notice of commercial marketing may be given only after FDA licensure.[1] (*See* Pet. App. 18a-22a.) At a minimum, the Government's inconsistent statements and omissions demonstrate the need for further percolation. This was the first case to address the patent provisions of subsection 262(*l*), and although the panel's decision now governs the specific questions that were before it, future cases will shed additional light on the statute and how its various pieces work together. Until that occurs, this Court's involvement would be premature and could produce unintended consequences.

If, however, the Court grants Sandoz's petition, it should also grant Amgen's conditional cross-petition. Indeed, the Government recommends granting Amgen's conditional cross-petition to review the integrated provisions of subsection 262(*l*) together to "ensure that the parties would be able to raise the full set of arguments in support of their positions." (U.S. Br. 24; *accord id.* at 1, 12-13.) Although the real lesson is that review should be denied entirely at this time, the Government is correct that if the Court takes one part of the case, it should also grant Amgen's conditional cross-petition.

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[1] The Government's brief could be read to suggest that Judge Chen dissented from the entirety of the Panel's decision regarding subparagraph 262(*l*)(8)(A). (*See* U.S. Br. 11-12.) The panel was unanimous that notice is effective only if given after FDA licensure. Judge Chen's dissent addressed whether an Applicant that fails to provide the subparagraph 262(*l*)(2)(A) disclosure must still give that notice.

I. THE GOVERNMENT'S BRIEF REINFORCES THAT THE COURT SHOULD DENY SANDOZ'S PETITION

A. The Federal Circuit Correctly Construed Subparagraph 262(*l*)(8)(A) and There Is No Reason To Grant Sandoz's Petition

1. The Text of Subparagraph 262(*l*)(8)(A) Demonstrates That Notice of Commercial Marketing Must Follow FDA Licensure

Subparagraph 262(*l*)(8)(A) provides that the Applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." This Court's review of that provision would necessarily begin with its language, yet the Government all but ignores the verb in the sentence. It never cites or distinguishes any of this Court's clear precedents establishing that the verb "shall" is generally mandatory. *See, e.g., Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 661-62 (2007); *Lopez v. Davis*, 531 U.S. 230, 241 (2001); *United States ex rel. Siegel v. Thoman*, 156 U.S. 353, 359-60 (1895).

Nor does the Government offer any satisfactory explanation for why Congress used the words "the biological product licensed under subsection (k)" in this provision but elsewhere in subsection 262(*l*) always refers to the product that "is the subject of" the subsection (k) application. *See* 42 U.S.C. §262(*l*)(1)(D), (*l*)(2)(A), (*l*)(3)(A)(i), (*l*)(3)(B)(i), (*l*)(3)(B)(ii)(I), (*l*)(3)(C), (*l*)(7)(B). The Government suggests that "product licensed" is used because the

product will be licensed when commercial marketing begins. (*See* U.S. Br. 14.) That is inherent; marketing without licensure is illegal. If subparagraph 262(*l*)(8)(A) ended ". . . before the date of the first commercial marketing of the biological product that is the subject of the subsection (k) application," marketing would still have to follow licensure, and thus this argument cannot explain Congress's word choice.

The careful distinction in Congress's word choice is reinforced by provisions of the BPCIA that the Government ignores: subparagraphs 262(k)(6)(A) and (C)(ii). (*See* Amgen Opp'n 18-19.) Those provisions help define the length of exclusivity as against other biosimilar products that is afforded to the first biosimilar that demonstrates "interchangeability" with respect to the reference product. Here, "commercial marketing" and "approval" are used with respect to the same product, and they suggest that commercial marketing will follow approval by six months. That provides strong support for the 180-day notice in subparagraph 262(*l*)(8)(A) being given after FDA licensure, yet the Government makes no attempt to square its reading with these provisions.

2. Subparagraph 262(*l*)(8)(A) Does Not Confer Six Months of Exclusivity

The Government argues that because the timing of market entry for biosimilars was "a significant issue addressed by the BPCIA," and given the 12-year exclusivity period in paragraph 262(k)(7), it is "particularly unlikely that Congress would have further delayed biosimilars' marketing in such an

indirect manner" as to require the 180 days' notice to be given after FDA licensure. (U.S. Br. 14-15.)

The Federal Circuit rightly rejected this argument. Subparagraph 262(*l*)(8)(A) does not confer "exclusivity." Instead, the 180-day notice period helps ensure an orderly litigation process, even when, for example, the BPCIA is applied retroactively to biologic products that had been on the market more than 12 years when the BPCIA was enacted.

Moreover, even during the twelve-year data "exclusivity" period of paragraph 262(k)(7), another company may obtain FDA approval of its version of a biologic product under the traditional subsection 262(a) pathway, using its own clinical efficacy and safety data. Indeed, another pharmaceutical company, Teva, did that for filgrastim, obtaining approval of its filgrastim product, GRANIX®, under subsection 262(a). (*See* Amgen Opp'n 23.)

Nor does the 180-day-notice requirement under subparagraph 262(*l*)(8)(A) extend even the limited data exclusivity provided during the 12-year period. The notice requirement is specific to each individual Applicant. For example, if the FDA ever approves Apotex's proposed biosimilar filgrastim product, Amgen will continue to face competition from both Sandoz's ZARXIO® and Teva's GRANIX® products while Apotex gives 180 days' notice to facilitate an orderly preliminary-injunction process. Amgen will enjoy no market exclusivity during that period.

Nor would there be anything unusual about delays of market entry extending beyond the expiration of a data-exclusivity period. The Hatch-

Waxman Act, which the Government contends is "analogous to" aspects of the BPCIA (U.S. Br. 2), grants periods of data exclusivity with respect to chemical medicines, 21 U.S.C. § 355(j)(5)(F)(ii), (iii). It also provides for a stay of FDA approval of a generic's ANDA lasting up to 30 months if the patent owner commences timely litigation. *Id.* § 355(j)(5)(B)(iii). The 30-month stay can, and often does, cause a product to remain off the market past the expiration of the data-exclusivity periods. The 180-day notice provision of subparagraph 262(*l*)(8)(A) is considerably more modest than the 30-month stay under the Hatch-Waxman Act.

The Government expresses concern that an Applicant with a new biosimilar license might have to "wait 180 days after FDA has authorized it to commence marketing, even if the sponsor had no arguably valid infringement claim to warrant such delay." (U.S. Br. 14.) The Government wrongly assumes that the list of potentially applicable patents is fixed at the end of the information exchange under paragraph 262(*l*)(3) or the filing of litigation under paragraph 262(*l*)(6). That ignores paragraph 262(*l*)(7). If a patent is newly issued to, or newly exclusively licensed by, the Sponsor after it has provided the subparagraph 262(*l*)(3)(A) list, the Sponsor must supplement that list within 30 days, triggering further information exchange. *See* 42 U.S.C. § 262(*l*)(7). Such a patent is then explicitly included within subparagraph 262(*l*)(8)(B), which the Government overlooks.

3. The "Fully Crystallized Controversy" Refers to the Need for a Preliminary Injunction

The Government goes to great length to criticize the Federal Circuit's observation that requiring notice after FDA licensure would help ensure a "fully crystallized controversy," but its criticism misconceives the purpose of the provision and the Federal Circuit's logic.

The Government conflates judicial resolution of substantive patent disputes with the grant of an injunction. It notes that because the Applicant could, if it chose, force all of the patents listed on the subparagraph 262(*l*)(3)(A) and (*l*)(3)(B) lists to be included in what it calls the "Round 1 litigation," there is already a fully crystalized, litigable controversy on all of those patents long before FDA licensure. (U.S. Br. 15-16.)

That wrongly equates the existence of an Article III controversy with the availability of equitable relief. The reason that there is a controversy sufficient to support patent-infringement litigation is that Congress made the filing of an aBLA under the subsection 262(k) pathway an act of infringement, either for the patents listed by the Sponsor and Applicant in the paragraph 262(*l*)(3) exchanges or, if the Applicant fails to provide its subparagraph 262(*l*)(2)(A) disclosure, for any patent the Sponsor could have listed in those exchanges. *See* 35 U.S.C. § 271(e)(2)(C)(i), (ii).

Whether there is a basis to sue on a technical act of infringement, however, is a very different inquiry

than the public-interest-oriented and litigant-specific factors that a district court must consider in deciding whether to grant injunctive relief. Among those factors are the irreparability of harm in the absence of preliminary relief, the public interest, and the likelihood of success on the merits. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). That is why the Federal Circuit referred to a "fully crystallized controversy regarding the need for injunctive relief." (Pet. App. 21a (emphasis added).) Tellingly, the Government omits the underlined words. The 180-day notice requirement, as interpreted by the Federal Circuit, provides the Sponsor and the courts with critical information and certainty regarding when the biosimilar will actually be first commercialized and, by virtue of the FDA license, what the biosimilar is, how it will be made, and for what therapeutic uses it will be sold. As the Federal Circuit explained, "[w]e believe that Congress intended the notice to follow licensure, at which time the product, its therapeutic uses, and its manufacturing processes are fixed." (*Id.*) All of those facts, which crystallize only at final approval, inform whether there is imminent need for judicial action, providing a concrete basis for application of the preliminary-injunction factors. Allowing an Applicant to provide notice long before its application is approved by the FDA would defeat that purpose.

4. If Notice Cannot Be Enforced, Then Notice Is Illusory

The Government contends that "no federal cause of action exists under which a sponsor could obtain

injunctive relief if the applicant fails to give notice as specified in Section 262(*l*)(8)(A)." (U.S. Br. 13.) That position is in tension with the many places where the Government touts the virtue of pre-marketing notice. (*See, e.g.*, *id.* at 17-18.) The Government recognizes, for example, that "Congress concluded that a sponsor should be given a fair chance to litigate the Round 2 patents prior to actual marketing" and that "Subsection (*l*)(8)(A)'s notice requirement therefore is properly viewed as affording the sponsor an adequate opportunity to commence litigation on the Round 2 patents" for which it could not sue during what the Government calls "Round 1." (*Id.* at 18.)

If an Applicant cannot be compelled to provide the 180-day notice, then those Congressional purposes are gutted. An Applicant could provide its aBLA under paragraph 262(*l*)(2), exchange information under paragraph 262(*l*)(3), defer until Round 2 all but one of the listed patents under paragraph 262(*l*)(5), wait until it obtains FDA licensure to announce that it was refusing to provide notice under subparagraph 262(*l*)(8)(A), and then immediately begin commercial marketing. The Sponsor would have to seek a temporary restraining order, having lost its "fair chance to litigate the Round 2 patents prior to actual marketing." (*See id.* at 18.) And the federal district court would face a technologically intensive, hurried injunction motion, what Judge Taranto described as the "reliability-reducing rush." *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1063 (Fed. Cir. 2016), *cert. denied*, 580 U.S. __ (Dec. 12, 2016).

B. This Court Should Permit BPCIA Case Law To Develop Further in the Lower Courts

In addition to confirming the flaws in Sandoz's attack on the Federal Circuit's construction of subparagraph 262(*l*)(8)(A), the Government's brief also confirms the wisdom of denying Sandoz's petition to allow these issues to percolate further in the lower courts.

Various inconsistencies and logical leaps in the Government's brief likewise highlight how early this case arises and the dangers of this Court adjudicating one portion of the statute before additional cases flesh out other provisions of the BPCIA. For example:

• The Government assumes that preliminary-injunctive relief during the 180-day notice period is "expressly limited to claims involving" the "Round 2" patents. (U.S. Br. 17.) The text of the statute does not support this. Nothing in subparagraph 262(*l*)(8)(A) limits the availability of injunctive relief to certain patents. Subparagraph 262(*l*)(8)(B) discusses those "Round 2" patents, but says nothing about being limited to them. No lower court has yet addressed this issue.

• The Government inconsistently suggests that submitting an aBLA is an act of infringement, while at other times suggesting that the Applicant's subsequent failure to provide the aBLA to the Sponsor creates the act of infringement. (*Compare* U.S. Br. 3, 6, *with id.* at 4-5.) It seems clear from the statute that submission of the aBLA is the technical act of infringement, but the lower courts

should be permitted to develop and clarify this area of law before the Court addresses it.

• The Government equates suing for patent infringement with seeking a declaratory judgment, and it therefore reads the limitations on declaratory judgments in paragraph 262(*l*)(9) as limitations on infringement suits. (*See, e.g.*, U.S. Br. 8, 16.) As the Federal Circuit recognized in *Apotex*, however, a declaratory-judgment action is not the same thing as an infringement suit, and a declaratory-judgment action seems a particularly poor "remedy" for some of the "fail[ures]" described in paragraph 262(*l*)(9). *See Apotex*, 827 F.3d at 1065. Before the Court simply accepts that infringement suits and declaratory-judgment actions are one and the same, as the Government suggests, it should have the benefit of lower court opinions addressing these issues.

There will be ample opportunity for swift further development of the law. The Federal Circuit has already addressed subparagraph 262(*l*)(8)(A) in the wake of *Sandoz*, in the *Apotex* case. The Federal Circuit currently has another BPCIA case before it addressing *Sandoz* and the proposition that where an Applicant refuses to provide other "manufacturing information" with its aBLA, the Sponsor may file suit and "'access the required information through discovery.'" (U.S. Br. 11 (quoting Pet. App. 17a-18a).) *See Amgen Inc. v. Hospira, Inc.*, No. 16-2179 (Fed. Cir. appeal docketed June 7, 2016).

This Court should deny Sandoz's petition and allow these issues to percolate further in the lower courts.

II. THE GOVERNMENT'S BRIEF REINFORCES THAT THE COURT SHOULD GRANT AMGEN'S CONDITIONAL CROSS-PETITION IF IT GRANTS SANDOZ'S PETITION

The Government agrees that if the Court grants Sandoz's petition it should grant Amgen's conditional cross-petition as well. (U.S. Br. 1, 13, 24.) Subparagraphs 262(*l*)(2)(A) and 262(*l*)(8)(A) "are integrally related," and the "proper interpretation of those provisions has a significant impact on the operation of the BPCIA." (*Id.* at 13.)

The Government's arguments themselves underscore the need for the Court to consider these two provisions in tandem, if at all.

First, the Government entirely ignores the Federal Circuit's rationale for why subparagraphs 262(*l*)(2)(A) and (*l*)(8)(A) should be treated differently. This case presents two statutory provisions using the same verb, yet the Federal Circuit construed one "shall" as mandatory and one as not mandatory. It rested that distinction on language in the BPCIA that it construed as specifying the exclusive consequences for a failure to comply with the first provision, and the absence of parallel language addressing the second provision. The Government glosses over this. This Court's review of the Federal Circuit's construction of one provision would necessarily implicate the other, however. If one is considered, they should be reviewed together.

Second, the Government proposes a rule under which disclosure by the Applicant is not required under either provision: The Applicant cannot be compelled to provide its aBLA and manufacturing information under subparagraph 262(*l*)(2)(A) or pre-marketing notice under subparagraph 262(*l*)(8)(A). If accepted, those positions would negate the balance that Congress sought to achieve in the BPCIA, and would impose intolerable burdens on Sponsors and federal district courts, promoting launch-at-risk tactics that imperil patient continuity of care, as described above. The Court should review both provisions together as part of a unitary disclosure scheme.

Third, under the Government's reading, a Sponsor may never be able to access information about the Applicant's manufacturing process. Without the aBLA and manufacturing information, the Sponsor would have to guess what patents to assert. And without 180 days' notice, the Sponsor would have to request, receive, digest, and sue on highly technical information in the compressed rush of a preliminary-injunction motion. Details will get missed. Valid claims will go unasserted. And Sponsors may never be able to assert manufacturing patents. This consequence, too, compels review of both provisions together if the Court reviews either.

CONCLUSION

The Court should deny Sandoz's petition. If the Court grants that petition, it should also grant Amgen's conditional cross-petition.

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DECEMBER 20, 2016